TORNIER

510(k) Summary

510(K) Owner's Name:	Tornier Inc.
Address:	10801 Nesbitt Avenue South Bloomington, Minnesota 55437
Phone and Fax Numbers:	Phone: 952.426.7600 Fax: 952.426.7601
Name of Contact Person:	Janell A. Colley
Date Prepared:	December 5, 2013
Trade or Proprietary Name:	Tornier Aequalis Humeral Nail System
Common or Usual Name:	Intramedullary Fixation Rod
Classification Name:	Product Code: HSB 21 CFR 888.3020
Legally Marketed Device to Which Your Firm Is Claiming Equivalence:	Tornier Aequalis Humeral Nail System, K082754
Description of The Device:	The Tornier Aequalis Humeral Nail System includes intramedullary nails and screws. The Tornier Aequalis Humeral Nail is a straight, cannulated intramedullary nail with a tapered distal diameter. Nails are provided in right and left configurations with a 9mm diameter and 130mm length. The proximal end of the nail contains screw holes in four axes for proximal locking using 5mm cannulated or non-cannulated screws. The proximal end of the nail also contains a cannulated polyethylene insert with screw holes aligned with those of the nail. This insert is intended to help prevent the proximal screws from backing out. The distal end of the nail incorporates one screw hole for distal locking using 4.5mm screws. The nail and screws are manufactured from anodized Ti-6Al-4V alloy. The purpose of this 510(k) is to add 7mm or 8mm proximal diameter nails in lengths of 130mm, 210mm, 230mm, 250mm, and 270mm lengths to the predicate system.
Intended Use of the Device:	The Tornier Aequalis Humeral Nail System is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact humeral head, or Humeral Fractures according to Neer-Classification (2, 3 and 4 part fractures).
Technological Characteristics Compared To Predicate Device:	The technological characteristics (material, design, sizing, indications, sterilization, and failure strength) of the Tornier Aequalis Humeral Nail System are substantially equivalent to the predicate device.
Summary of the Nonclinical Tests Submitted:	Non-clinical laboratory assessment/testing was performed to evaluate the device performance per design requirements and risk analysis, including bending calculation comparisons and torque testing. All tests met the pre-established acceptance criteria.
Conclusions Drawn From the Nonclinical and Clinical Tests:	Based on risk analysis and acceptable results from testing, the Tornier Aequalis Humeral Nail System was found to be substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 5, 2013

Tornier, Incorporated
Ms. Janell A. Colley
Regulatory Affairs Manager
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

Re: K133376
Trade/Device Name: Tornier Aequalis Humeral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 6, 2013
Received: November 7, 2013

Dear Ms. Colley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TORNIER

Statement of Indications for Use

510(k) Number: **K133376**

DEC 05 2013

Device Name: Tornier Aequalis Humeral Nail System

Indications for Use

The Tornier Aequalis Humeral Nail System is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact humeral head, or Humeral Fractures according to Neer-Classification (2, 3 and 4 part fractures).

Prescription Use ___X____ AND/OR Over-The-Counter Use___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

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